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January 29, 2001

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Via Certified Mail - Return Receipt Requested

Mr. John M. Whealan Office of the Solicitor United States Patent and Trademark Office P.O. Box 15667 Arlington, Virginia 22215 SOLICITOR

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U.S. PATENT & TRADEMSKI CHROE

Re:

Purepac Pharmaceutical Co. v. Andrx Pharmaceuticals, Inc.

Civil Action No. 00-CV-1224

Dear Mr. Whealan:

This firm represents Purepac Pharmaceutical Co., the plaintiff, in the above-referenced action which is pending in the United States District Court for the Eastern District of Pennsylvania.

On Friday, January 26, 2001, the Court endorsed a Stipulated Order Modifying the Protective Order that had been entered in the action in order to permit Purepac to disclose to the PTO, on a confidential basis in accordance with § 724.02 of the MPEP, certain information relating to Purepac's pending Patent Application Numbers 09/606,629 and 09/447,642.

Paragraph 3 of the Stipulated Order requires that we serve a copy of the Stipulated Order upon you by certified mail, return receipt requested. Accordingly, a copy is enclosed. A copy of the Stipulated Order and the Protective Order it modifies will accompany Purepac's disclosure to the PTO.

If you wish to discuss this matter for any reason, please contact me.

Respectfully.

James W. Kennedy

of PAUL, HASTINGS, JANOFSKY & WALKER LLP

JWK:cmo Enclosure

cc:

James V. Costigan, Esq.

Dianne B. Elderkin, Esq. Steven Lee, Esq.

Messrs. Graff and Bensen ADDITIONAL NEW YORK OFFICE:

399 PARK AVENUE NEW YORK, NEW YORK 10022-4697

## IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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PUREPAC PHARMACEUTICAL CO.

Plaintiff,

FILED

Civil Action No. 00-CV- 1224

STIPULATED ORDER MODIFYING PROTECTIVE ORDER

ANDRY PHARMACEUTICALS, INC. 11 2 5 2001

Defendant

The parties have entered into, and this Court has endorsed, a Stipulated Protective Order, dated June 26, 2000, governing discovery in this action; and

Section 9 of said Protective Order provides that the "Protective Order may be modified by further order of this Court or by agreement of the parties or their counsel, subject to the approval of the Court, provided that any such agreement be in the form of a stipulation that shall be filed with the Court and made a part of the record in this case;" and

Plaintiff having asked the Court to enter an order modifying the Protective Order in order to allow plaintiff's disclosure to the United States Patent and Trademark Office ("PTO"), in connection with the pending patent applications identified below, of certain information that defendant has designated under the Protective Order as Confidential or Confidential Attorney's Eyes Only; and

Defendants having opposed Plaintiff's request and Counsel for the parties having conferred with the Court by telephone concerning plaintiff's request; and

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The Court having directed the parties to submit a stipulated order modifying the Protective Order to allow certain disclosure as set forth herein:

IT IS HEREBY STIPULATED AND AGREED by and between the undersigned counsel for the parties, and ORDERED, ADJUDGED AND DECREED by the Court, that

- 1. Notwithstanding any contrary confidentiality designation by defendant, the Protective Order is modified to allow Purepac's disclosure to the PTO, in connection with Purepac's pending patent application nos. 09/606, 629 ("629") and 09/447642 ("642"), of information, chosen by Purepac to be disclosed to the PTO pursuant to 37 CFR 1.56, contained in the notebooks of Chih-Meng Chen bearing production nos. 116295-480, 116482-613, 116615-74 and the transcript of the deposition testimony of Chih Meng Chen, dated November 17, 2000. In addition, so long as the '629 and '642 applications shall not have been canceled, withdrawn from consideration, issued or abandoned, plaintiff may also disclose to the PTO any and all information, chosen by Purepac to be disclosed to the PTO pursuant to 37 CFR 1.56, contained in additional testimony of Dr. Chen or any other of defendant's witnesses concerning Dr. Chen's notebooks or the experiments reflected in those notebooks. Prior to disclosure of such information, the plaintiff shall identify for defendant the specific portions of the aforementioned notebooks and transcripts plaintiff intends to disclosed to the PTO.
- The information described above shall only be disclosed in accordance with the provisions of Section 724.02 of the Manual of Patent Examining Procedure ("MPEP") governing the disclosure of material that is subject to a protective order, and shall be clearly labeled "Subject to Protective Order," as required by MPBP § 724.02. In addition to any other requirements of MPEP § 724.02, plaintiff shall provide the PTO with a copy of this Stipulated Order and the Protective Order it modifies, and shall advise the PTO that its disclosure of defendants'

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information is subject to the terms of this Stipulated Order and to the Protective Order. The PTO shall not exercise its authority, pursuant to 37 C.F. R. § 1.14 (see MPEP § 101), to release or make available to the public any of the information so disclosed and so labeled as Subject to Protective Order without first obtaining prior leave of this Court, on reasonable notice to the parties.

3. Prior to submission or disclosure of any documents by plaintiff to the PTO, plaintiff shall serve the Solicitor of the PTO with a copy of this order by certified mail, return receipt requested.

## RESPECTFULLY SUBMITTED:

HOYLE, MORRIS & KERR, LLP

By:

Stephen J. Mathes

One Liberty Place, Suite 4400

1650 Market Street

Philadelphia, Pennsylvania 19103

(215) 981-5700

Attorneys for Plaintiff

Purepac Pharmaceutical Co.

IT IS SO ORDERED:

Dated: January 25, 2001

WOODCOCK WASHBURN KURTS MACKIEWICZ & NORRIS, LLP

By:

Thomas D. Smith

One Liberty Place, 46th Floor

Philadelphia, Pennsylvania 19103.

(215) 568-3100

Attorneys for Defendant

Andrx Pharmaceuticals, Inc.

United States District Judge

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CLERK OF COURT

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